



Complete Summary

GUIDELINE TITLE

The levonorgestrel-releasing intrauterine system (LNG-IUS) in contraception and reproductive health.

BIBLIOGRAPHIC SOURCE(S)

The levonorgestrel-releasing intrauterine system (LNG-IUS) in contraception and reproductive health. J Fam Plann Reprod Health Care 2004 Apr; 30(2): 99-108; quiz 109. [97 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

- Unintended pregnancy
- Menorrhagia

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations and good practice points regarding the use of a levonorgestrel-releasing intrauterine system for contraception and other reproductive health benefits

TARGET POPULATION

Women considering the use of levonorgestrel-releasing intrauterine system

INTERVENTIONS AND PRACTICES CONSIDERED

1. Medical history and physical examination including
 - Bimanual pelvic examination
 - Testing for sexually transmitted infection
 - Measurement of pulse and blood pressure
 - Prophylaxis to prevent pelvic infection and bacterial endocarditis
 - Full blood count for treatment of menorrhagia
2. Assessment of medical eligibility for levonorgestrel-releasing intrauterine system (LNG-IUS)
3. Counseling women regarding the risks and benefits associated with LNG-IUS use and the timing of LNG-IUS insertion
4. All procedures and documentation required for LNG- IUS insertion (refer to the Faculty of Family Planning and Reproductive Health Care [FFPRHC] guideline "The Copper Intrauterine Device as Long-Term Contraception")
5. Management of LNG-IUS problems (refer to FFPRHC guideline "The Copper Intrauterine Device as Long-Term Contraception")
6. LNG-IUS removal

MAJOR OUTCOMES CONSIDERED

- Risks and benefits of levonorgestrel-releasing intrauterine system (LNG-IUS) use
- Efficacy of LNG-IUS as a contraception
- Reduction in menstrual blood loss and patient satisfaction in women using LNG-IUS for treatment of menorrhagia

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Electronic searches were performed for: MEDLINE (CD Ovid version) (1980-2003); EMBASE (1980-2003); PubMed (1980-2003); the Cochrane Library (to December 2003), and the US National Guideline Clearing House. The searches were performed using relevant medical subject headings (MeSH), terms, and text words. The Cochrane Library was searched for systematic reviews, meta-analyses, and controlled trials relevant to the levonorgestrel-releasing intrauterine system. Previously existing guidelines from the Faculty of Family Planning and Reproductive Health Care (FFPRHC), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO), and reference lists of identified publications were also searched. Similar search strategies have been used in the development of other national guidelines.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Selected key publications were appraised according to standard methodological checklists before conclusions were considered as evidence. Evidence was graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organizations.

Evidence tables (available on the Faculty Web site [www.ffprhc.org.uk]) summarise relevant published evidence on the levonorgestrel-releasing

intrauterine system (LNG-IUS), which was identified and appraised in the development of this Guidance.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation based on levels of evidence as follows:

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the grades of recommendation, based on levels of evidence (A-C, Good Practice Point), are provided at the end of the "Major Recommendations" field.

What should a clinician assess before considering levonorgestrel-releasing intrauterine system (LNG-IUS) use?

1. After counselling, the LNG-IUS is a suitable option for most women who need contraception and/or treatment for menorrhagia (Grade C).

After counselling about other contraceptive methods, women who are assessed as at a higher risk of sexually transmitted infection (STI) may still choose to use the LNG-IUS (Good Practice Point).

After considering other contraceptive methods, a woman may use the LNG-IUS within 3 months of treated pelvic infection, provided she has no signs or symptoms (Good Practice Point).

Women with a history of migraine with focal symptoms may use the LNG-IUS. If, however, migraine with focal symptoms develops in a LNG-IUS user, these new symptoms should be investigated and other contraceptive options discussed (Good Practice Point).

Non-hormonal contraception is most appropriate for a woman with a history of breast cancer. However, the LNG-IUS may be considered individually, and in consultation with the woman's breast surgeon (Good Practice Point).

2. Levels of LNG in breast milk are low with the LNG-IUS. Therefore, women who are breastfeeding and are 4 or more weeks postpartum may choose this method (Grade B).
3. Women using the LNG-IUS may be reassured that there is no evidence of reduced efficacy with liver enzyme-inducers or other drugs (Grade B).

What do women need to know before considering the LNG-IUS?

4. Women should be informed that the LNG-IUS works primarily by its effect on the endometrium, thus preventing implantation. In addition, effects on cervical mucus prevent sperm penetration. Most women will continue to ovulate (Grade B).
5. Women should be advised that the LNG-IUS is an effective, reversible method of contraception with a failure rate of less than 1 per 100 woman-years (Grade A).
6. Women should be informed that the failure rate of the LNG-IUS is similar to that of modern intrauterine devices (IUDs) (Grade A).
7. Women should be informed that the LNG-IUS is licensed for 5 years' use (Grade C).

All women using the LNG-IUS should be advised to return for review after 5 years' use to discuss the need for removal and replacement (Good Practice Point).

Women should be advised that a small increase in the risk of pelvic infection occurs following LNG-IUS insertion but thereafter the risk of infection is low (Good Practice Point).

8. Women can be reassured that the risk of ectopic pregnancy with the LNG-IUS is low (Grade A).
9. Women can be reassured that there is rapid return of fertility following LNG-IUS removal (Grade B).

10. Women should be informed that the most likely cause of LNG-IUS failure is expulsion. The risk of this happening is around 1 in 20 (Grade A).
11. Women may be informed that uterine perforation occurs in fewer than 1 in 1,000 LNG-IUS insertions (Grade B).
12. Women should be informed that the LNG-IUS can reduce menstrual blood loss by over 90% (Grade A).
13. Women should be informed that altered patterns of menstrual bleeding (prolonged bleeding and amenorrhoea) are common with the LNG-IUS (Grade A).
14. Women may be informed that, although hormonal symptoms are reported by LNG-IUS users, these are not significantly different from IUD users (Grade A).
15. Women may be reassured that, although ovarian cysts occur in LNG-IUS users, there is no significant increased risk compared to IUD users (Grade A).
16. Women may be reassured that there is no evidence to suggest the LNG-IUS has a detrimental effect on bone mineral density (Grade C).

All women considering the LNG-IUS should be informed of potential bleeding patterns and hormonal symptoms that may occur with this method of contraception (Good Practice Point).

What are the potential non-contraceptive uses of the LNG-IUS?

17. The LNG-IUS can be used as a first-line option to treat menorrhagia (Grade A).
18. The LNG-IUS is effective in the management of menorrhagia, even in the presence of fibroids (Grade C).
19. It is not generally recommended that the LNG-IUS be used if fibroids are distorting the uterine cavity (Grade C).
20. Surgery (hysterectomy, endometrial resection, or ablation) is more effective than the LNG-IUS in treating menorrhagia at 1 year (Grade A).
21. The LNG-IUS is as effective as conservative surgery (resection and ablation) in the management of menorrhagia after the first year (Grade A).
22. Patient satisfaction and quality of life appear similar following LNG-IUS or surgical treatment of menorrhagia (Grade A).
23. There is insufficient evidence to support the use of the LNG-IUS routinely for women with pain in the absence of heavy bleeding (Grade C).
24. Women using oestrogen replacement may choose the LNG-IUS to provide protection against hyperplasia and malignancy, but this is outside the current license (Grade A).
25. The LNG-IUS should not be used routinely as a treatment for endometrial hyperplasia or malignancy (Grade B).
26. Women may be advised that there is insufficient evidence that the LNG-IUS alone is effective in the treatment of premenstrual symptoms (Grade C).

When can the LNG-IUS be inserted?

27. Ideally, the LNG-IUS should be inserted in the first 7 days after the onset of menstruation (Grade C).
28. The LNG-IUS is not effective as emergency contraception (Grade C).

The LNG-IUS can be inserted at any time in a woman's cycle if it is certain she is not pregnant and has not been at risk of pregnancy in that cycle. Barrier contraception is advised for the next 7 days (Good Practice Point).

Which examinations and tests should be performed prior to LNG-IUS insertion?

- 29. All women considering the LNG-IUS should have examinations and tests as for insertion of any intrauterine method of contraception (Grade C).
- 30. Endometrial assessment (biopsy or ultrasound scan) is not routinely required prior to LNG-IUS insertion for the management of menorrhagia (Grade C).

What procedures and documentation are required for LNG-IUS insertion?

Procedures and documentation should follow those outlined for the IUD in the Faculty of Family Planning and Reproductive Health Care (FFPRHC) guideline "The Copper Intrauterine Device as Long-Term Contraception."

What follow-up is required following LNG-IUS insertion?

- 31. Women who present with persistent menorrhagia, despite LNG-IUS use, should be advised to return for further assessment of the uterine cavity (biopsy or ultrasound scan) to exclude pathology (Grade B).

A follow-up visit should be advised after the first menses, or 3 to 6 weeks after LNG-IUS insertion (Good Practice Point).

How are LNG-IUS problems managed?

- 32. Suspected perforation, lost threads, pregnancy, presence of actinomyces-like organisms, and pelvic infection should be managed as for IUD use (Grade C).
- 33. Women using the LNG-IUS who present with a change in pattern of bleeding should be advised to return for further investigation to exclude infection, pregnancy, and gynaecological pathology (Grade B).

When can the LNG-IUS be removed?

The LNG-IUS may be removed at any time if the woman wishes to conceive; otherwise unprotected sex should be avoided in the 7 days prior to removal (Good Practice Point).

Definitions

Grades of Recommendation based on levels of evidence as follows:

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Potential Benefits

Appropriate use of a levonorgestrel-releasing intrauterine system (LNG-IUS) for contraception and other reproductive health benefits

Specific Benefits

- The LNG-IUS can reduce menstrual blood flow by over 90%.
- The LNG-IUS is more effective than oral treatment in the management of menorrhagia.

POTENTIAL HARMS

Risks associated with levonorgestrel-releasing intrauterine system (LNG-IUS):

- A small increase in the risk of pelvic infection occurs following LNG-IUS insertion.
- The failure rate is less than 1 per 100 woman-years.
- The most likely cause of LNG-IUS failure is expulsion. The risk of expulsion is around 1 in 20.
- Uterine perforation occurs in fewer than 1 in 1,000 LNG-IUS insertions.
- Altered patterns of menstrual bleeding are common with LNG-IUS.
- Overall hormonal symptoms such as acne, headache, breast tenderness, nausea, prolonged bleeding, embedded device, or pelvic inflammatory disease are not significantly different from intrauterine device users.
- There is a slight increase in the occurrence of ovarian cysts at 3 to 6 months after LNH-IUS insertion.

Risks associated with LNG-IUS use outweigh the benefits in the following circumstances:

- Thromboembolic disease: current deep vein thrombosis or pulmonary embolus
- Continuation in women with migraine with focal symptoms at any age
- Current trophoblast disease: benign
- Liver disease: active viral hepatitis
- Cirrhosis: severe decompensated
- Benign and malignant liver tumors

CONTRAINDICATIONS

CONTRAINDICATIONS

The levonorgestrel-releasing intrauterine system should not be used in the following circumstances:

- Current trophoblast disease: malignant
- Breast cancer: current
- Initiation in women with endometrial and cervical cancer

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

The levonorgestrel-releasing intrauterine system (LNG-IUS) in contraception and reproductive health. J Fam Plann Reprod Health Care 2004 Apr; 30(2): 99-108; quiz 109. [97 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Apr

GUIDELINE DEVELOPER(S)

Faculty of Family Planning and Reproductive Health Care - Professional Association

SOURCE(S) OF FUNDING

Faculty of Family Planning and Reproductive Health Care

GUIDELINE COMMITTEE

Clinical Effectiveness Committee

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Edinburgh); and Dr Alison Vaughan (Director of Contraceptive Services, East Dorset/Education Committee Representative)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Family Planning and Reproductive Health Care Web site](#).

Print copies: Available from the Faculty of Family Planning and Reproductive Health Care, 27 Sussex Place, Regent's Park, London NW1 4RG

AVAILABILITY OF COMPANION DOCUMENTS

Discussion points and questions for levonorgestrel-releasing intrauterine system, developed by the Faculty of Family Planning and Reproductive Health are available at the end of the original guideline document.

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Family Planning and Reproductive Health Care Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

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